

“Mullis”). Claims 3-6 and 8 would be allowable if rewritten to be in independent form and to overcome the rejection for indefiniteness.

Telephonic Interview with the Examiner

Applicants thank the Examiner for the telephonic interview on November 5, 2002, and provide remarks based on comments made in that interview. In addition, Applicants submit the figure that was transmitted to the Examiner as part of that interview as an aid in understanding the differences between the prior art and the present invention.

Rejections under 35 U.S.C. §112, second paragraph

Claims 2-5 are rejected for indefiniteness, with the Examiner stating, “[I]t is still unclear what is meant by the language ‘3000-fold range of specificity’....” As an initial matter, Applicants note that the language “3000-fold range of specificity” only appears in claim 4, and thus, the rejection of claims 2, 3, and 5 for indefiniteness should be withdrawn. Furthermore, as applied to claim 4, this rejection is respectfully traversed. The definition of “range of specificity” is given on page 6 of the specification. This definition reads:

By “range of specificity” is meant the range of nucleic acid template:PCR primer ratios at which template sequences differing by at least one nucleotide may be discriminated by assaying for the presence of detectable PCR amplification product formation.

Applicants note that “specificity” in this context means the ability to amplify a target sequence preferentially over non-target sequences. This preferential amplification occurs

not just at one concentration of primer and target but over a range of concentrations of primer and target. This range is thus referred to as the "range of specificity." In general, the term "3000-fold" describes a range where the upper limit is 3000 times the lower limit, e.g., 1 – 3000 is a 3000-fold range. As applied to a range of specificity, the modifier "3000-fold" means that the highest concentration at which a target sequence is preferentially amplified is 3000 times the lowest concentration at which the target sequence is preferentially amplified. In view of the foregoing, the rejection of claims 2-5 for indefiniteness should be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 1-2, 7, 9, and 14-20 stand rejected for anticipation by Sorenson. Applicants traverse this rejection and direct the Examiner's attention to the enclosed figure, which graphically illustrates one key difference between the present invention and Sorenson.

Claims 1 and 15, the independent claims rejected, are directed to a method and a kit for determining whether a nucleic acid sequence comprises a particular allele of a polymorphic sequence. Each of these claims requires first and second pairs of primers, characterized as follows:

- (i) one of said first pair of PCR primers is (a) complementary at its 3'-terminal nucleotide to a first allele of said polymorphic sequence...
- (ii) one of said second pair of PCR primers is (a) complementary at its 3'-terminal nucleotide to said first allele of said polymorphic sequence...

Thus, claims 1 and 15 require two primers that have the same nucleotide at their 3' termini. This feature is illustrated in the enclosed figure under the heading "Claimed invention." In this example, a primer from the first pair and a primer from the second pair have a T at their 3' ends, each of which is complementary to the A in the first allele (boxed in the figure). In contrast, Sorenson teaches the use of "four primers [that] are unique with respect to each other and differ ... at the 3' nucleotide which is complementary to the wild type nucleotide or to one of the three possible mutations which can occur at this known position." (Col. 2, ll. 30-34; Emphasis added). The method of Sorenson is illustrated in the Sorenson patent at Figure 1B and is represented in the enclosed figure under the heading "Sorenson reference." In the figure and the attached representation, fours primers are present, and each primer has a different 3' terminal nucleotide. Accordingly, only one of these primers can possibly have a 3' nucleotide that is complementary to a "first allele." Therefore, Sorenson does not teach the use of two primers that are each complementary to a first allele at their 3' ends as required by independent claims 1 and 15, and the rejection for anticipation should be withdrawn.

Rejections under 35 U.S.C. §103(a)

Claims 10, 12, and 13 stand rejected as being obvious over Sorenson in view of Mullis. Applicants respectfully disagree. Claim 10, from which claims 12 and 13 depend, is directed to the method of claim 1 with the additional limitation that certain of the primers include a unique hybridization tag. As stated above, Sorenson does not teach

or suggest the method of claim 1, and Mullis does not remedy this deficiency. Therefore, the combination of Sorenson and Mullis fails to teach or suggest the methods of claims 10, 12, and 13, and the §103 rejection should be withdrawn.

Change of Address

Effective immediately, please address all communication in this application to:

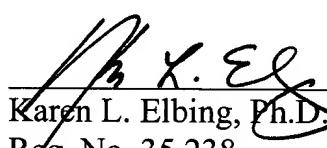
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CONCLUSION

Applicants submit that the claims are in condition for allowance and such action is requested. Enclosed is a petition to extend the period for reply for two months, to and including November 18, 2002. If there are any additional charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 12 November 2002


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